1C082623

CONFIDENTIAL

510(k) SUMMARY

FEB 25 2009

General Information

Submitted by:

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Contact Person:

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Date Prepared: August 29, 2008

Device Name

Trade Name: Visix Imaging
Common Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp. (purchased by Televere Systems)	TigerScan/TigerView	K955237

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Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card, or SCSI card.

Intended Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Technological Comparison

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Visix Imaging has been demonstrated to perform as intended.

Conclusions

Visix Imaging is substantially equivalent to legally marketed Picture Archiving and Communications Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Televere Systems
% Ms. Barbara Deay
Technical Support and Writing
Televere Systems
471 Stage Road
CHARLTON NY 12019

Re: K082623
Trade/Device Name: Visix Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2009
Received: January 14, 2009

Dear Ms. Deay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082623

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiologic[illegible]
510(k) Num[illegible] K082623 August 29, 2008